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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,885	10/19/2004	Martin Purpura	5942-83616	4212

22242 7590 09/28/2007
FITCH EVEN TABIN AND FLANNERY
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CHICAGO, IL 60603-3406

EXAMINER

MAEWALL, SNIGDHA

ART UNIT	PAPER NUMBER
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1615

MAIL DATE	DELIVERY MODE
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09/28/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/511,885

Applicant(s)

PURPURA ET AL.

Examiner

Snigdha Maewall

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13-21 and 23-29 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13-21 and 23-29 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. ____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Summary

1. Receipt of Preliminary amendment and IDS filed on 06/27/2007, 07/10/2007 and 08/24/2007 is made of record.

Claims 12 and 22 are cancelled. Claims included in this application are **1-11, 13-21** and **23-29** and will be prosecuted on the merits.

Information Disclosure Statement

The listing of references in the Search Report is not considered to be an information disclosure statement (IDS) complying with 37 CFR 1.98. 37 CFR 1.98(a)(2) requires a legible copy of: (1) each foreign patent; (2) each publication or that portion which caused it to be listed; (3) for each cited pending U.S. application, the application specification including claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion, unless the cited pending U.S. application is stored in the Image File Wrapper (IFW) system; and (4) all other information, or that portion which caused it to be listed. In addition, each IDS must include a list of all patents, publications, applications, or other information submitted for consideration by the Office (see 37 CFR 1.98(a)(1) and (b)), and MPEP § 609.04(a), subsection I. states, "the list ... must be submitted on a separate paper." Therefore, the references cited in the Search Report have not been

Art Unit: 1615

considered. Applicant is advised that the date of submission of any item of information or any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the IDS, including all "statement" requirements of 37CFR 1.97(e). See MPEP § 609.05(a).

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 23 and 24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for reducing fat, does not reasonably provide enablement for preventing fat absorption. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. **To "prevent" is to keep from happening.**

For rejections under 35 U.S.C. 112, first paragraph, the following factors are considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988):

- I) Nature of the invention.
- II) State of prior art.
- III) Level of ordinary skill in the art.

- IV) Level of predictability in the art.
- V) Amount of direction and guidance provided by the inventor.
- VI) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

I. Nature of the invention:

The claims are drawn to a method for preventing elevated serum cholesterol levels and diabetes symptoms, for strengthening mental fitness and/or for exercising tolerance and fitness in a subject comprising the claimed functional food and a pharmaceutical preparation for preventing elevated serum cholesterol levels and diabetes symptoms, strengthening mental fitness, exercising tolerance and fitness, comprising the claimed functional food.

Applicants' specification does not discuss or show with data how the recurrence of elevated serum cholesterol levels and diabetes symptoms associated with the claimed functional food is avoided.

II. State of the prior art:

The prior art does not disclose case supported by data showing a method for preventing elevated serum cholesterol levels and diabetes symptoms, for strengthening mental fitness and/or for exercising tolerance and fitness in a subject comprising the claimed functional food and a pharmaceutical preparation for preventing elevated serum

Art Unit: 1615

cholesterol levels and diabetes symptoms, strengthening mental fitness, exercising tolerance and fitness, comprising the claimed functional food.

III. Level of Ordinary Skill in the art:

The level of ordinary skill in the art is high. Applicants' specification does not enable the public to practice the art of keeping elevated serum cholesterol levels or diabetes symptom from happening.

IV. Level of predictability:

Since applicants' specification does not show the stoppage or exclusion or keeping a method for preventing elevated serum cholesterol levels and diabetes symptoms, for strengthening mental fitness and/or for exercising tolerance and fitness in a subject comprising the claimed functional food and a pharmaceutical preparation for preventing elevated serum cholesterol levels and diabetes symptoms, strengthening mental fitness, exercising tolerance and fitness, comprising the claimed functional food from happening, the ability of the person of skill in the art is challenged to extrapolate the disclosed or known results to the claimed invention with little or no predictability. The lower the predictability, the higher the direction and guidance that must be provided by the applicants. In the instant invention the predictability is very low and consequently, the need for the higher levels of direction and guidance by the applicants.

V. Amount of direction and guidance provided by the inventors:

The amount of direction and guidance provided by the applicants is limited to treating elevated serum cholesterol levels or diabetes symptoms but not preventing them for ever.

VI. Quantity of experimentation needed to make or use the invention based on the content of the disclosure:

The quantity of experimentation required to use the invention as claimed, based on applicants' disclosure would be undue burden because, one of ordinary skill in the art would have to perform significant amount of experimentation with a large number of subjects and for reliable duration of time during which elevation of serum cholesterol levels or diabetes symptom or the fitness strengthening as claimed is kept from happening.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-11, 13-21 and 23-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1615

Regarding claims 1,4,5, 6 13 and 17 the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the broad recitation polymers and minerals and the claim also recites silicates and mixtures thereof, which is the narrower statement of the range/limitation.

Claims 11 and 13, 17 recite the limitation "derivatives thereof". The metes and bounds of the claim are not defined. Claim 1 recites the limitation "starting material of acetone insoluble phospholipids components". It is not clear which compounds are included and which are not. Claims 13 and 17 recite the limitations "mono and disaccharides and their sugar alcohols", "trace elements", "mineral substances and

suitable derivatives thereof". The claims are rendered indefinite because the metes and bounds of the claims are not defined.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-11, 13-21 and 23-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kiliaan et al. (WO 01/84961 A2) in view of Geiss (US PG pub. 2004/0120985 A1) and further in view of Hochschild (US Patent No. 4,374,082).

Kiliaan et al. discloses a preparation suitable for the prevention and/or treatment of vascular disorders, comprising the following fractions: fraction a) long chain polyunsaturated fatty acids; fraction b) phospholipids, the fraction contains at least two different phospholipids selected from the group consisting of phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine, fraction c) compounds which are a factor in methionine metabolism, which fraction contains at least one member selected from the group consisting of folic acid, vitamin B 12, vitamin B6, magnesium and zinc (abstract). The preparation of the invention can be a pharmaceutical, dietetic as well as a nutritional

Art Unit: 1615

preparation. The products can have the form of a liquid, powder, bar, cookie, sweetie, concentrate, paste, sauce, gel, emulsion, tablet, capsule, etc. to provide the daily dose of the bioactive components either as a single or in multiple doses (page 6, lines 1-5).

Triglyceride is listed on page 6, line 14. The composition contains zinc and copper (see page 9, lines 1-5). Kiliaan et al. discloses on page 12, various diseases and symptoms that can be treated are cognitive degeneration and improper functioning associated with kidneys, liver, stomach etc. another advantage of the composition disclosed is in normalizing plasma cholesterol levels (see page 6, lines 17-18).

Kiliaana et al. do not teach unmodified carbohydrate and protein.

However, Geiss et al. discloses functional food for the cognitive functional capacity comprising carbohydrate, proteins, phosphatidylserine, vitamins and fat. The functional food products disclosed are in the form of milk, diet foods, dairy products etc. (see claims).

Geiss does not teach granular preparation of the formulation. However, Hochschild teaches a method of making a solid pharmaceutical or nutritional dosage form that is suitable for oral administration and is in granular form (see abstract and column 1, lines 30-31, lines 54-57, column 2, lines 58-59 and example on column 4).

It would have been obvious to the one of ordinary skilled in the art at the time the invention was made to incorporate carbohydrate and protein (unmodified) in the composition forwarded by Kiliaana et al. because unmodified carbohydrate and protein in the form of functional food help in enhancing cognitive functions. A skilled artisan would have been motivated to formulate a functional food comprising unmodified

Art Unit: 1615

carbohydrate and protein along with vitamins, minerals and phospholipids for treating cognitive functions and other medical conditions as discussed above with a reasonable expectation of success. It would have been further obvious to the one of ordinary skilled in the art to formulate matrix comprising the claimed components motivated by the guidance provided by Hochschild to prepare a phospholipids containing stable matrix with a reasonable expectation of success.

With respect to various amounts claimed in the instant application, it is the position of the examiner that optimization of such parameters would have been within the purview of a skilled artisan by doing experimental manipulations. Applicant is reminded that where the general conditions of the claims are met, burden is shifted to applicant to provide a patentable distinction. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See *In re Aller*, 220 F.2d 454 105 USPQ 233,235 (CCPA 1955).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone

Art Unit: 1615

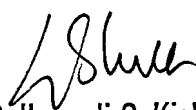
number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Snigdha Maewall

Art Unit

1615


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